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IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS

ROBERT CARR,

Plaintiff,

Case Number:

VS.

JUDGE:

ZIMMER, INC.; ZIMMER HOLDINGS, INC.; WILSON/PHILLIPS HOLDINGS, INC. a/k/a ZIMMER WILSON PHILLIPS, AND ZIMMER ORTHOPAEDIC SURGICAL **MAGISTRATE JUDGE:**

PRODUCTS, INC.,

COMPLAINT

Defendants.

JURY DEMAND

COMES NOW the Plaintiff, ROBERT CARR (hereinafter referred to as "Plaintiff"), by and through undersigned Counsel, and for his Complaint against the Defendants, alleges as follows:

NATURE OF THE CASE

- 1. This is an action for damages suffered by Plaintiff, as a direct and proximate result of Defendants placing into the stream of commerce an unreasonably dangerous product and Defendants'negligence in connection with the development, design, manufacture, distribution, and selling of Defendants' knee replacement product, the Zimmer NexGen CR and the Zimmer NexGen CR-Flex Porous Femoral knee replacement system (hereinafter "Zimmer NexGen Knee").
- 2. The Zimmer NexGen Knee prematurely loosens in patients, such as Plaintiff, causing personal injury, significant pain, and loss of movement, and that this injury can only be remedied through subsequent knee revision surgery.

PARTIES

- 3. Plaintiff is a citizen of the State of Illinois, and a resident of Chicago, Illinois.
- 4. Defendant Zimmer, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business located in Warsaw, Indiana.
- 5. Defendant Zimmer Holdings, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business located in Warsaw, Indiana.
- 6. Defendant Wilson/Phillips Holdings, Inc. a/k/a Zimmer Wilson Phillips is a corporation organized and existing under the laws of Texas, and has its principal place of business in Richardson, Texas.
- 7. Defendant Zimmer Orthopaedic Surgical Products, Inc. is a corporation organized and existing under the laws of Ohio, and has its principal place of business in Dover, Ohio.
- 8. At all times material hereto, Defendants developed, designed, tested, manufactured, distributed, marketed, and sold the Zimmer NexGen Knee.
- 9. At all material times, Defendants' products, including the Zimmer NexGen Knee, were sold throughout the world, including within the State of Illinois.

JURISDICTION AND VENUE

- 10. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds \$75,000 exclusive of interest and costs.
- 11. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. § 1391(a), as a substantial number of the events, actions or omissions giving rise to Plaintiff's claims occurred in this district. At all times material hereto, Defendants conducted substantial business in this district.

FACTUAL BACKGROUND

KNEE REPLACEMENT BACKGROUND

- 12. Total knee arthroplasty (TKA), also called total knee replacement, is a common medical procedure performed. The surgery is designed to help relieve pain and improve joint function in people with severe knee degeneration due to arthritis or trauma.
- 13. The TKA procedure is typically done by separating the muscles and ligaments around the knee to expose the inside of the joint. The ends of the thigh bone (femur) and the shin bone (tibia) are removed as is often the underside of the kneecap (patella).
- 14. Generally the results of total knee arthroplasty in long-term reports are very good with prosthetic survival rates of 92–99 % at 14–17 years (Font-Rodriquez et al. 1997¹, Gill and Joshi 2001², Keating et al. 2002³).
- 15. Mechanical loosening means that for some reason (other than infection) the attachment between the artificial knee and the bone has become loose.
- 16. Loosening of an artificial knee can be diagnosed by among other things using an X-ray. In patients with a loose knee joint there may be one or more radiolucent lines around the contours of the artificial knee joint.
- 17. A loose knee replacement may cause metal or plastic wear particles to circulate in the knee joint; cause joint inflammation and swelling; and cause olsteolysis or loss of bone in the regions around the knee, resulting in pain and disability for the patient.

¹ Font-Rodriques, DE et al (1997), Survivorship of cemented total knee arthroplasty, Clin. Orthop 345: 79-86

² **Gill** GS, **Joshi** AB. SO. Long-term results of cemented, posterior cruciate ligament-retaining total knee arthroplasty in osteoarthritis, Am J Knee Surg. **2001**;14(4):209-14

³ **Keating, E. Michael MD; Meding, John B. MD; Faris, Philip M. MD; Ritter, Merrill A. MD** Long-Term Followup of Nonmodular Total Knee Replacements Clinical Orthopaedics & Related Research: November 2002 - Volume 404 - Issue - pp 34-39

- 18. Once the pain becomes unbearable or the individual loses function of the knee, and/or the knee becomes unstable another operation will typically be required to revise the knee replacement. A loose, painful artificial knee can usually, but not always, be revised.
- 19. The purpose of knee revision surgery is to remove a failed knee implant and replace it with a new one. In a revision operation of a total knee has failed, the orthopaedic surgeon must remove the components used for the original surgery. The orthopaedic surgeon's goal is to restore stability and alignment to the knee, adding bone graft if needed, custom wedges or trabecular metal wedges or augments, and often using revision implants.
- 20. Generally the results of a revision operation are not as good as the initial TKA, and the risks of complications are higher.

THE ZIMMER NEXGEN KNEE

- 21. Zimmer was founded in 1927, and purports to be a worldwide leader in the design and manufacture of orthopaedic reconstructive, spinal and trauma devices, dental implants, and related orthopaedic surgical products.
- 22. The Zimmer NexGen Knee uses a "high-flex" porous femoral component made of a cobalt-chromium-molybdenum alloy. A porous coat of sintered titanium metal is applied to the surfaces of the implant that are designed to contact bone (see red arrow below). In this fashion the femoral component is designed to achieve stability by having the patient's own bone grow into the femoral implant. In addition Zimmer designed and manufactured the femoral component of the NexGen CR High Flex knee with a larger posterior buildup (see green arrow

below). This design was intended to achieve a greater degree of flexion or bending of the knee.



- 23. Defendants manufactured, labeled, packaged, distributed, supplied, marketed, advertised, and/or otherwise engaged in all activities that are part and parcel of the sale and distribution of a medical device, and by said activities, caused the Zimmer NexGen Knee to be placed into the stream of commerce throughout the United States.
- 24. The Zimmer NexGen Knee has been widely advertised, marketed and represented by the Defendants as a safe and effective medical device for use in TKA procedures.
- In 2010, Dr. Richard A. Berger, a Zimmer consultant, and his colleague Dr. CraigJ. Della Valle, presented a paper at a national meeting of the American Association of

⁴ Zimmer web site

 $<\!\!H\underline{http://www.google.com/imgres?imgurl=\!http://www.zimmer.nl/uploads/pics/P_Knee.jpg\&imgrefurl=\!http://www.zimmer.nl/producten/knie/\&usg=_2-$

 $[\]frac{2 \text{UbxAzAq0On8sMygAsn5APMAM} = \&h=400\&\text{w}=550\&\text{sz}=24\&\text{h}\\ = \text{en}\&\text{start}=0\&\text{sig2}=\text{KGa3rHee0Cp0UuEJtX6C}}{QQ\&\text{zoom}=1\&\text{tbnid}=\text{Gcy} \text{ KrQ34LPzYM}: \&\text{tbnh}=156\&\text{tbnw}=222\&\text{ei}=\text{YBBUTZfqGNS2twePr8nrCg\&prev}=/\text{imag}}\\ = \text{es}\%3\text{Fq}\%3\text{Dnexgen}\%2\text{Bhigh}\%2\text{Bflex}\%2\text{Bcr}\%2\text{Bzimmer}\%2\text{6hl}\%3\text{Den}\%2\text{6as}_\text{st}\%3\text{Dy}\%2\text{6biw}\%3\text{D1916}\%2\text{6bih}\%}\\ 3\text{D847}\%2\text{6tbs}\%3\text{Disch}:1,isz:lt,islt:qsvga&itbs=1\&iact=rc\&\text{dur}=485\&\text{oei}=\text{YBBUTZfqGNS2twePr8nrCg}\&\text{esq}=1\&\text{p}}\\ = \text{age}=1\&\text{ndsp}=33\&\text{ved}=1\text{t:}429,\text{r:}29,\text{s:}0\&\text{tx}=100\&\text{ty}=69}\text{H}> \text{last visited February }10^{\text{th}}, 2011.}$

Orthopedic Surgeons showing that approximately 9% percent of their patients who had the Zimmer NexGen Knee implanted required revision surgery and 36% showed signs of the knee implant loosening within one year of implant.⁵

ALLEGATIONS SPECIFIC TO PLAINTIFF

- 26. On November 7, 2006, an orthopaedic surgeon implanted a Zimmer NexGen Knee into the Plaintiff in the City of Chicago, County of Cook and State of Illinois.
- 27. Plaintiff began experiencing severe and debilitating pain approximately one year after implant. Plaintiff returned to Plaintiff's physician and was advised his Zimmer NexGen Knee was experiencing "loosening" and would need to be revised.
- 28. In March 2010, Plaintiff had a second surgery to revise/replace his previously implanted Zimmer NexGen Knee.
- 29. Plaintiff did not discover, nor could he have discovered through the exercise of reasonable care, the defective nature of the Zimmer NexGen Knee until after the surgery of March 10, 2010. Further, in no way could Plaintiff have known that Defendants had designed, developed, and manufactured the Zimmer NexGen Knee in such a way as to increase the risk of harm or injury to the recipients of it until after March 10, 2010.

COUNT I

(Strict Liability)

- 30. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.
- 31. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of Zimmer NexGen Knee. Defendants designed,

⁵ Craig J Della Valle, Richard A Berger, et a. The High Failure Rate of a High-Flex Total Knee Arthroplasty Design. Paper no. 434, Scientific Program – Podium2010 Annual Meeting AAOS, New Orleans, Louisiana, March 9 – 13.

manufactured, marketed, and sold Zimmer NexGen Knee to medical professionals and their patients, knowing it would be implanted for knee replacements.

- 32. The Zimmer NexGen Knee as designed, manufactured, marketed and sold by Defendants reached Plaintiff without substantial change in its condition and was used by Plaintiff in a reasonably foreseeable and intended manner.
- 33. The Zimmer NexGen Knee was "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that Zimmer NexGen Knee was in a condition not suitable for their proper and intended use among patients.
- 34. The Zimmer NexGen Knee was used in the manner for which it was intended, that is, for artificial knee replacement. This use resulted in injury to Plaintiff.
- 35. The Zimmer NexGen Knee is defective in design because of its propensity to loosen and cause patients unnecessary pain and repeat surgical procedures and because it was sold without adequate warnings regarding, inter alia, the propensity of Zimmer NexGen Knee to loosen and cause serious pain and necessitate additional surgery; the post-marketing experience of higher rates of loosening and revision surgery with the Zimmer NexGen Knee; and the probability of suffering loosening and revision surgery.
- 36. As a direct and proximate result of the Zimmer NexGen Knee's defective and dangerous design and inadequate warnings as aforesaid, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, pain and suffering, and the loss of a normal life all to Plaintiff's damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages plus costs of suit and for such other and further relief as the court deems equitable and just.

COUNT II

(Negligence)

- 37. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.
- 38. At all relevant times, Defendants had a duty to exercise reasonable care in the design, testing, manufacture, marketing, sale, and distribution of Zimmer NexGen Knee.
- 39. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of Zimmer NexGen Knee because Defendants knew or should have known that Zimmer NexGen Knee had a propensity to cause serious injury, including loosening and revision surgery and failed to provide adequate warnings to the implanting doctors and the general public regarding the risk of serious injury, including, loosening and revision surgery.
- 40. As a direct and proximate result of Defendants' acts and omissions as aforesaid, Plaintiff suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, pain and suffering, and loss of a normal life all to Plaintiff's damages.

WHEREFORE, Plaintiff demand judgment against Defendants for compensatory damages plus costs of suit and for such other and further relief as the court deems equitable and just.

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JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

DATED this 10 day of February, 2011.

By: /s/ Peter J. Flowers

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CERTIFICATE OF SERVICE

I hereby certify that on February 10, 2011, I electronically filed the foregoing document with the
clerk of the court for the U.S. District Court, Northern District of Illinois, using the electronic case filing
system of the Court.

/s/ Peter Flowers